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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/596,114	06/16/00	GROSSMAN	HMR2050

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HM12/0509

EXAMINER

LOEB, B

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.		Applicant(s)	
	09/596,114		GROSSMAN ET AL.	
	Examiner		Art Unit	
	Bronwen Loeb		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06/16/00 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input checked="" type="checkbox"/> Other: <i>detailed action</i> |

DETAILED ACTION

This action is in response to the Election in Response to the Restriction Requirement dated March 30, 2001. Claims 1-27 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-18 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the subject matter of Groups II-VII are sufficiently related such that a thorough search for the vector of Group I would encompass a search for the subject matter of the methods of using it, and that a search and examination of the entire application could be made without serious burden. This is not found persuasive because burden is presumed for different inventions and was established in the Restriction Requirement based on the recognized divergent subject matter and the different classifications of the different inventions. A thorough search for the vector of Group I does not encompass the subject matter of the methods of using the vector as evidenced by the different classification of Group I from Groups II-VII. The classification of Group I (class 435, subclass 320.1) currently contains over 9000 patents. Searching this class alone for the invention of Group I represents a serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the citizenship of each inventor.

Specifically, the citizenship of inventor Paul August is omitted.

Sequence Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers, no computer readable format (CRF) was filed, no paper sequence was filed and no attorney statement was filed. These sequences include **Figures 7, 8 and 9, p. 19, line 20 and p. 20, line 14**. If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

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Specification

4. The disclosure is objected to because of the following informalities: on p. 12, line 1 there is an unknown symbol "(□)".

Appropriate correction is required.

Drawings

5. The drawings are objected to because Figure 4 has language in the lower left hand corner unrelated to the figure contents ("Trudy Grossman..."). Correction is required.

Claim Objections

6. Claim 16 is objected to because of the following informalities: the abbreviation BAC is not defined at its first use in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 13, 15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Claim 13 is drawn to a specific vector, pTRANS-SacB. Claim 15 is drawn to a specific vector, pTRANS. Claim 18 is drawn to a specific vector, pBacTA.PUC2. Because it is not clear that the identical vectors are freely available or can be reproducibly isolated from nature a biological deposit for patenting purposes is required.

The requirements for description and enablement may be met by depositing the cell line in a recognized depository. If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant or a statement by an attorney of record over his or her signature and registration number, stating that the specific material has been deposited under the Budapest Treaty and that the material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the requirements of 37 CFR 1.801-1.809 (see Federal Register, Vol. 54, No. 161, issued August 2 1989), Applicant may provide assurance of compliance by an affidavit or declaration or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Applicant must furthermore submit a viability statement consisting of:

- (1) the name and address of the depository;
- (2) the name and address of the depositor;

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- (3) the date of deposit;
- (4) the identity of the deposit and the accession number given by the depository;
- (5) the date of the viability test;
- (6) the procedures used to obtain a sample if the test is not done by the depository; and
- (7) a statement that the deposit is capable of reproduction.

A viability statement is not required for deposits made under the Budapest Treaty.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 9, 11, and 14 recite the word "containing" which is vague and indefinite because it is not legally defined as open or closed language. It is suggested that language be amended to recite "comprising" or "consisting of" as is appropriate.

Claim 16 recites the phrase "improved BAC vector" which renders the claim vague and indefinite as it is unknown over what the vector is improved. It would be remedial to delete the word "improved" from the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. Claims 1-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al (USP 5,645,991). Berg et al teach a vector comprising a bacterial transposon, $\gamma\delta$, within which is an origin of replication (ori) from pUC19 plasmid (ColE1), which is a high copy number ori. The vector further comprises a T7 promoter and an SP6 promoter, a kanamycin resistance gene, a tetracycline gene and an ampicillin gene, and a *sacB* and a *strA* gene as counterselectable markers. See entire document, especially col. 1, lines 19-27, col. 2, lines 43-63, col. 3, lines 19-26, col. 3, line 63- col. 4, line 15, and col. 5, line 1-col. 6, line 35.

13. Claims 1-7, 9, 10 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Reznikoff et al (USP 5,948,622). Reznikoff et al teach a vector comprising a bacterial transposon, Tn5, within which is a high copy number origin of replication, ColE1. The vector further comprises an antibiotic gene, such as kanamycin or ampicillin resistance. The vector also comprises a second selectable marker that can be distinguished from the first selectable marker. The vector comprises the T7 promoter. See entire document, especially Figures 1, 4 and 9, col. 11, lines 11-42 and col. 24, lines 11-13.

14. Claims 1, 2, 5-7, 14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Marsch-Moreno et al (1998 Plasmid 39: 205-214). Marsch-Moreno et al

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teach a vector comprising Tn5-derived mobile element within which is a ColE1 origin of replication, a high copy number ori. The vector comprises a kanamycin resistance gene. The vector comprises transcription control sequences for the trp, tet and neo genes. The origin of replication, derived from pBR322, is flanked by *Nci* I sites, which leaves single base extensions. The vector further comprises a *Bst* XI site. See entire document, especially Abstract, p. 206-207, Construction of pTn5cat and Figure 1.

Conclusion

Claims 1-18 are rejected. Claims 13, 15 and 18 are free of prior art.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to Dianiece Jacobs, Patent Analyst whose telephone number is (703) 305-3388.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

May 4, 2001


ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER